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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,544	05/30/2001	R. Rox Anderson	910000-2001	1057
20999	7590	03/11/2005	EXAMINER	
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			FARAH, AHMED M	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/870,544	<b>Applicant(s)</b> ANDERSON ET AL.	
	<b>Examiner</b> Ahmed M Farah	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on 03 December 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-23 and 25-50 is/are pending in the application.
- 4a) Of the above claim(s) 40-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-23,25-39 and 46-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-23, 25-39 and 46-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zavislan et al. U. S. Patent No. 5,860,967 in view of Sinofsky U.S. Patent No. 5,071,417.

As to claims 1, 15, 16, 20, 34, 35, 39, 46, and 48-50, Zavislan et al. disclose apparatus and method for non-invasively identifying and locating one or more subsurface targets based on predetermined conditions for selective laser treatment at a tissue surface, the apparatus comprising:

means for directing one of polarized and an unpolarized light having a predetermined wavelength at a tissue site (see Fig. 3);

means (**CCD** camera) for detecting one or more reflections of light using a multi-dimensional photo-sensor;

means for determining and/or displaying the location and one or more characteristics of the subsurface tissue based upon the detected reflections (see the abstract); and

means (laser **20** and laser controller **24**) for selectively treating one or more subsurface targets using a laser beam of a predetermined wavelength and power in accordance with the tissue characteristics.

As to claims 2, 3, 21 and 22, the determined characteristics include at least the size, shape, and photometric properties of the tissue at one or more subsurface targets.

As to claims 4-6 and 23-25, the controller means **24** pulses the laser beam and adjusts one or more parameters of the laser beam, such as spot size, pulse width, etc.

As to claims 7, 8, 26 and 27, the spot size of the laser beam is adjusted through the movement of focusing lens **42**.

As to claims 12 and 31, the feedback system is controlled by both the operator and computer system. Hence, it is a semi-automatic feedback control.

As to claims 13 and 32, the spot size used by Zavislan et al. is about 500 microns, which is less than 3 mm (see col. 4, lines 58-64).

As to claims 18, 37 and 47, the system of Zavislan et al. further comprises a means for determining a polarization of one or more reflections, wherein the location and one or more characteristics of the subsurface target are determined based upon said polarizations as presently claimed (see col. 6, lines 1-11).

As to claims 19 and 38, the treatment laser beam heats the target tissue thereby modifying the characteristics of said tissue.

However, although the controller system of Zavislan et al. is capable to provide a real time adjustment of the treatment laser in accordance with a desired treatment, they

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do not particularly teach a closed loop system as recited. Nevertheless, the use of a feedback control system for non-invasive treatment of a patient is known in the art.

Sinofsky discloses a system and method of use for fusion of biological tissue, the system comprising:

means for directing a laser light (one of polarized and an unpolarized light) having a predetermined wavelength at a tissue site, said laser light heating the tissues at the target site;

means (reflectance monitor **18**) for detecting one or more reflections of light using a multi-dimensional photo-sensor;

means (display **24**) for determining and/or displaying the location and one or more characteristics of the subsurface tissue based upon the detected reflections (see Fig. 1); and

means (controller **16**, laser **12**, and tuner **26**) for selectively treating one or more subsurface targets using a laser beam of a predetermined wavelength and power in accordance with the tissue characteristics.

As to claims 9, 11, 28 and 30, the reflectance monitor performs real time monitoring/tracking of the target tissue; and the laser delivery unit **20** directs the treatment laser in response to the detected signals. Therefore, in the system of Sinofsky, the directing, detecting, and the determining functions are performed in real time (i.e., rapid feedback for tracking rapid relative movement between the treatment system and target site).

As to claims 10 and 29, the rapid feedback has a bandwidth of more than 0.5 HZ. This is due to the fact that for the tracking to be in real time, the response time of the system (the time between the detection of the reflected system, analyzing the data, and determining the tissue parameter, such as its location) must be much less than 2 seconds. Therefore, even if the response time is about 1 second, the rapid feedback has a bandwidth of 1 HZ, which is more than the recited 0.5 Hz.

As to claims 14 and 33, Sinofsky teaches that his invention is practiced with a wide variety of laser sources, including continuous wave ("c.w.") or pulsed modes (see col. 4, line 68 to col. 5, line 2).

As to claims 17 and 36, the feedback control is one of a closed-loop and quasi-closed-loop feedback control as presently claimed.

Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to use a closed loop system to adjust, in real time, at least one or more parameters of the treatment energy in accordance with the desired treatment so as to reduce treatment time. The use of a feedback control, closed-loop system would obviate the need of manual errors and operator delays.

### ***Conclusion***

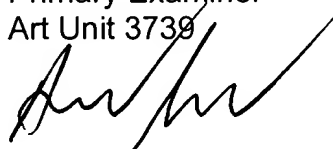
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M Farah whose telephone number is (571) 272-4765. The examiner can normally be reached on Mon-Thur. 9:30 AM-7:30 PM, and 9:30 AM - 6:30 PM on every other Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M DVorak can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ahmed M Farah  
Primary Examiner  
Art Unit 3739



03/05/2005.